Applicant's Response to §102 Rejection:

The Examiner has rejected claim 19 under 35 U.S.C. §102(a) as being anticipated by Myers et al. (WO 95/05132). The Examiner has also rejected claim 19 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,700,285 to Myers et al. Applicant will address these rejections together as they stem from the same document.

More specifically, the Examiner states:

> **Myers et al. discloses a braided stent (see Figure 9) intimately bound (see Figure 8) to a biaxially expanded PTFE graft; see the whole document. For this reason, the claim language is fully met because the stent and graft would inherently expand and contract together such that the expansion ratios thereof would be virtually the same; in other words, less than 25% as claimed.**

The present invention is directed to an expandable prosthesis including a discontinuous wall defining a lumen which is radially contracatable and expandable (stent). The prosthesis further includes a polytetrafluoroethylene (PTFE) layer which is affixed to the discontinuous wall (covering). The ability of the prosthesis to expand and contract is dependent upon the ability of the covering to expand and contract with the stent. Further, the invention provides a prosthesis which expands and contracts by providing a PTFE covering which expands and contracts with the expansion and contraction of an expandable stent.

As set forth in independent claim 19 of the present invention, such expansion and contraction is provided by employing a layer of ePTFE which is defined by spaced apart nodes interconnected by fibrils. Claim 19 further specifically claims a shortening of average longitudinal inter-nodule distance.

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This shortening inter-nodule distance is wholly absent from Myers. There is no discussion within Myers regarding the use of the ePTFE covering with a stent which longitudinally shortens when intradially expands. Furthermore, there is no discussion in Myers as to a gradient between inter-nodule distance of ePTFE after radial expansion. There is still further no suggestion by the Examiner that these are present. Instead the Examiner states that the claim language is fully met because the stent and graft would, "inherently expand and contract together such that the expansion ratios thereof would be virtually the same."

It is clear that the Examiner has the burden of establishing a *prima facie* case of anticipation with respect to the rejection under 35 U.S.C. §102. Anticipation requires that each and every element of the claimed invention be found in the reference. The Examiner has failed to make a *prima facie* showing that Myers discloses each and every element set forth in claim 19.

Specifically, the Examiner has failed to show where Myers discloses a different longitudinal internodule distance in the radial expanded and contracted state. Moreover, the Examiner has provided no support or explanation as to why such internodule distance gradient would be inherent.

Absent a *prima facie* showing by the Examiner, Applicant need not rebut the Examiner's unsupported assertions. Myers therefore does not disclose the present invention as claimed, and Applicant should not be asked to disprove something not specifically recited in the reference. Removal of the rejection under 35 U.S.C. §102 based upon Myers is respectfully solicited.

Applicant's Response to §103 Rejection:

The Examiner has rejected claim 20 under 35 U.S.C. §103(a) as being

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unpatentable over Banas, et al. (U.S. Patent No. 5,749,880) in view of Wallsten (U.S. Patent No. 4,954,126). More specifically, the Examiner states:

> **Banas et al. discloses many stent types (see column 12, line 49 et seq.) which can be bonded to uniaxially expanded PTFE with no nodules (only nodes, See Figure 18A to 19B). However, Banas fails to specifically disclose using a braided stent as claimed. Wallsten, however, teaches that it was known to the art to make braided self-expanding stents. Hence, It is the Examiner's position that it would have been obvious to use a braided self-expanding stent, as taught by Wallsten, for the same reasons that Wallsten desires the same and so that self-expansion and even distribution of pressure can be brought to the Banas et al. device.**

Claim 20 of the present invention recites, "at least one layer of uniaxially oriented polytetrafluoroethylene affixed to the stent, the polytetrafluoroethylene characterized by having substantially **no nodules**."

A close review of Figures 18a to 19b of Banas reveals an ePTFE structure comprised of nodules, or nodes, connected by fibrils in the typical construction of ePTFE. Each of Figures 18a through 19b, and, in fact, the entire specification and claims, discuss ePTFE with this node [or nodule] and fibril relationship.

Furthermore, at column 22, lines 61-67, the specification states, "from each of Figures 18a - 20b, it can readily be seen that when the stent-graft is radially expanded, the ePTFE node-fibril microstructure undergoes little elongation in the axis of radial expansion while the bonded area of sintered ePTFE in the wall thickness remains integrally and monolithically bonded, and substantially without interlayer demarcation."

With regard to rejections under 103 as well as rejections under 102 Applicant again submits that the Examiner has the burden of establishing a *prima facie* case of

obviousness. The Examiner has failed to make a *prima facie* showing of obviousness as neither reference discloses a polytetrafluoroethylene structure characterized by having substantially **no nodules**. There is still further no teaching or suggestion in any reference cited by the Examiner of an ePTFE structure with substantially **no nodules**.

Absent a *prima facie* showing by the Examiner, Applicant need not rebut the Examiner's unsupported assertions. It is respectfully submitted that the rejection based on 35 U.S.C. §103 is improperly based. Removal of the rejection is respectfully solicited.

For the reasons set forth, withdrawal of the rejections and favorable reconsideration is respectfully requested. Should the Examiner have any questions regarding this response or wish to discuss this matter in further detail, please contact the undersigned attorney.

Respectfully submitted,

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VERSION OF AMENDMENTS WITH MARKINGS SHOWING CHANGES MADE

IN THE SPECIFICATION:

Please delete the first paragraph of page 1 of the specification and insert therefor:

~~This application claims the benefit of United States Provisional Application No. 60/007,435, entitled EXPANDABLE STENT GRAFT COVERED WITH EXPANDED POLYTETRAFLUOROETHYLENE filed November 21, 1995.~~ The present application claims priority to and is a divisional application of copending application U.S. Serial No. 08/988,725, now U.S. Patent No. 6,165,211, filed December 11, 1997, which is a divisional application of U.S. Patent No. 5,788,626 filed November 18, 1996, which claims priority to provisional application No. 60/007,435, filed November 21, 1995.

Please delete the first paragraph of page 3 of the specification and insert therefore:

In sum, the present invention relates to an expandable prosthesis having (a) a discontinuous wall defining a lumen adapted to assume a longitudinally contracted position and a longitudinally expanded position; and (b) at least one layer of expanded polytetrafluoroethylene having a first average longitudinal inter-nodule distance in a free state, the layer of polytetrafluoroethylene affixed to the wall such that it has a second average longitudinal inter-nodule distance when the wall is in the longitudinally contracted position, the second average longitudinal inter-nodule distance being less than the first average longitudinal inter-nodule distance. The layer of expanded polytetrafluoroethylene may have (i) an average longitudinal inter-nodule distance of between about 0 and about 50 microns, preferably between about 5 and

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about 45 or between about 20 and about 30 microns, when the wall is in the longitudinally contracted position, and (ii) an average longitudinal inter-nodule distance of between about 50 and about 150 microns, preferably between about 60 and about ~~14~~ 140 or between 80 and about 120 microns, when the wall is in the longitudinally expanded position.

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